K003036

DEC 22 2000

Premarket Notification [510(k)] Summary

Submitter: RetinaLabs.com, Inc
1776 Peachtree Street Suite 200 North
Atlanta, GA 30309

Phone: (404) 815-5233
Fax: (404) 873-3582

Official Correspondent: Frank J. Tighe

Trade Name: The RetinaLabs.com, Inc., Turbo-Flow Infusion Cannula

Common Name: Fluid/Air Infusion Cannula

Registration Number: 1063514

Class: Class 1

Class Name: 21 CFR 886.4670

Panel: Ophthalmic

Product Code: KYG

Device Description: The RetinaLabs.com, Inc. Turbo-Flow Infusion Cannula is a sterile device composed of a stainless steel cannula and soft silicone tubing. The device is used to infuse fluid and/or air during ophthalmic vitreoretinal surgery. Please see Device Replica Diagram in Appendix B.

Statement of indications for use. - For infusion of fluid and air during vitreoretinal eye surgery.

Substantial Equivalence Comparison

	RetinaLabs.com	Grieshaber
Materials: Stainless/Silicone tubing	X	X
For infusion of fluid/air in ophthalmic surgery.	X	X
Sterilization ETO	X	X

Sterility

The Device will be ETO Sterilized.

The method used to validate the sterilization cycle is AAMI Overkill Method.

Packaging Material: Tyvek Pouch with a Ploymylar Sheath.

The SAL is 10 to the –6.

The maximum levels of residues of **ethylene oxide**: 25 parts per million; **ethylene chlorohydrin:** 25 parts per million and **ethylene glycol:** 250 parts per million.

This device is non-pyrogenic and the LAL Method is used to make that determination.

Pyrogens: We control the manufacturing environment to lessen the likelihood of pyrogen causing bacteria. In addition the LAL Method is used to determine that each lot is non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 2000

Mr. Frank J. Tighe
RetinaLabs.com, Inc.
1776 Peachtree Street Suite 200 North
Atlanta, GA 30309

Re: K003036
Trade Name: Turbo-Flow™ Infusion Cannula
Regulatory Class: I
Product Code: 86 KYG
Regulation: 886.4670
Dated: September 21, 2000
Received: September 29, 2000

Dear Mr. Tighe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K003036

510(k) Number: N/A

Device Name: Turbo-Flow™ - Infusion Cannula

Indications For Use: For infusion of fluid and air during vitreoretinal eye surgery.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ OR Over-The-Counter Use _____
(Per 21 CFR 8O1.109)

(Optional Format 1-2-96)

M L B Nicholas
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003036

OR/Y

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